Loughborough University

Health and Safety Department

Biological Safety Policy

Version No: 1

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Contents

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1. Overview

1.1 Purpose

It is the policy of Loughborough University to ensure that all work involving the use of biological material is subject to the standards of control necessary to prevent, or where this is not possible to minimise, risks to human health, safety and the environment.

Effective biological safety management requires consideration of the safe, responsible, sustainable and economical use of biological material – from procurement, storage, use, transport and through to disposal. All aspects of biological material use are governed by a comprehensive set of legislation to ensure the risks posed by substances which may be harmful to health or to the environment are suitably controlled.

1.2 Scope

This policy applies to all work (handling, use, transportation, storage and disposal) involving Genetically Modified Organisms (GMO), microorganisms, cell cultures, parasites, human or animal tissue (including blood, urine and other body products) or plant material which gives rise to a risk of infection, allergy or toxicity or have a detrimental effect on the wider environment.

The policy applies to:

- All staff, students (both postgraduate and undergraduate) and personnel (e.g. contractors and visitors) at workplaces under the control of Loughborough University.
- All ACDP Hazard groups (1-4) biological material classified as hazardous under Control of Substances Hazardous to health (COSHH) Regulations 2002
- All materials that may contain biological materials (including blood, bodily fluids)
- All genetically modified organisms as classified under the Genetically Modified Organisms (Contained Use) Regulations 2014
- Animal pathogens covered under Specified Animal Pathogen Order 2008
- Controlled or prohibited plants, plant products or plant seeds under section 1-6 of the Plant Health Order 2015
- Biological Material that are covered under Schedule 5 of the Anti-Terrorism, Crime and Security Act 2001
- All work carried out with Waste Water

Please note there are additional policies/procedures for biological material that falls under the Human Tissue Act and Ethics Approval. Please see the University HTA Licence Compliance Quality Manual and University Ethics guidelines for further information

HTA Licence Compliance Quality Manual

2. Key Legislative Requirements

2.1 Control of Substances Hazardous to Health Regulations (COSHH) 2002

2.2 Genetically Modified Organisms (Contained Use) Regulations 2014

2.3 Other Key Legislation

- Specified Animal Pathogen Order 2008
- Plant Health Order 2015
- Anti-Terrorism, Crime and Security Act 2001
- Animal By-Products (Enforcement) (England) Regulations 2013
- The Controlled Waste (England and Wales) Regulations 2012
- The Hazardous Waste (England and Wales) Regulations 2005
- Pollution Prevention and Control Act 1999
- Environmental Protection Act (EPA) 1990 Part II (Waste on Land)
- The Hazardous Waste (Miscellaneous Amendments) Regulations 2015

3. Duty Holders

3.1 Deans of Schools/Heads of Professional Services

Deans of Schools/Heads of Professional Services shall:

- Ensure that systems are in place to control the purchasing or acquisition of any biological material.
- Ensure that systems are in place to comply with this policy.
- Ensure that adequate resources are made available to implement this policy. In particular:
    - Allocate sufficient resources to install and maintain effective control measures in accordance with statutory requirements
    - Provide training for staff to comply with this policy
- Seek confirmation from School/Service staff that arrangements are still effective
- Appoint responsible person to manage biological safety if warranted within the School (Responsible Person) or School Safety Officers
- Ensure training and competencies for all relevant staff and student
- Ensure safe disposal of all biological material

3.2 School/Department Safety Officers or Responsible Person (RP)

SSO's/DSO's/RP shall monitor the effectiveness of any control measures and make recommendations to the Dean of School/Head of Service as necessary. In particular:

- Monitor that all biological material is introduced into the School/Service in accordance with local procedures and that an inventory of biological material is kept
- Assist in training of all staff, students and visitors
- Audit risk assessments documentation to verify that suitable and sufficient assessment are in place and up to date and that the biological material is in the correct hazard group/GM class.
- Ensure that all work involving biological material at a classification of hazard group 2 (including unscreened blood) is sent to the University Biological Safety Officer for final approval before work commences.
- Ensure all work involving genetically modified organisms or novel work with biological material in classes 1 and 2 is subject to peer review by members of the GM/Biological Safety Committee before work commences.
- Ensure no work is carried out using hazard group 3-4 biological material or GMO2 or above.
- Hazard signs are maintained, and security arrangements are implemented to prevent unauthorised access.
- All biological material is autoclaved or treated by another validated waste treatment method immediately prior to its disposal.
- Suitable personal protective equipment (PPE) is provided where appropriate and is maintained to a good order. Reusable items are regularly examined for faults, damage, wear and tear.
- Ensure that LEV (for example microbiological safety cabinets) equipment is used appropriately, that members of staff are trained in their safe use and that problems with LEV performance are promptly reported to the Facility Services. LEV found to be operating below the standard appropriate for the type of use it is being put to, are to be taken out of use pending repair.
- Verify that plant, equipment and engineering controls are maintained in accordance with the agreed schedule
- Ensure safe disposal of all biological material
- Ensure equipment, work areas are decontaminated, and appropriate clearance permits are completed prior to decommissioning and transferring to alternative locations (see University Biological Safety Officer for advice)
- Emergency procedures are set out to deal with exposures to biological material within their School's including puncture wounds, spillages or airborne release.
- Liaise with occupational health service to arrange health surveillance as required.
- Report accidents of near misses involving exposure to biological material to the UH&SS and the University Biological Safety Officer

3.3 Line Managers/Academic Supervisors

Staff who are responsible for managing the activities carried out by students, staff or volunteers are considered as laboratory or academic supervisors. As such they have a duty to ensure the health and safety of the students/staff they supervise and have responsibilities where their students/staff handle biological material.

Line managers are responsible for the health and safety of the staff/students they manage and others who may be affected by their work.

Line Managers/Academic Supervisors will ensure:

- The risks posed by the use and handling of biological materials are assessed before starting and action is taken to prevent or control exposure so far as reasonably practicable
- If the work involves Human Tissue, to stop prior to work commencing and seek further guidance from the HTA team within the School or University Designate Individual. http://www.lboro.ac.uk/committees/human-tissue-authority-licence/
- Personnel they manage/supervise are competent to work with the material and have been provided with sufficient information and training on the risk posed by the biological material they use and the control measures in place
- Equipment is used correctly and maintained in an efficient state and good working order.
- Risk assessments are reviewed and updated regularly (every 2-3 years), when significant changes occur or following an incident.
- Ensure using the hierarchy of control to facilitate the risk assessment process.
- Ensure equipment and work areas they are responsible for are decontaminated are use or when being removed from laboratories.
- Ensure that on completion of a project or when staff/students they manage leave the School/Service all biological material they are responsible for are either disposed of appropriately using University Clinical Waste procedures or responsibility is transferred to another responsible person. Transfer must be Information must be given to DSO/SSO

3.4 University Biological Safety Officer/Health & Safety Service

The University Biological Safety Officer (UBSO) shall:

- Produce, and as often as necessary, review the Biological Safety Policy and associated guidance documents
- Monitor compliance with this policy
- On request provide information and guidance to staff/students on working with biological material or potential biological material
- Review and authorise all Hazard group 2 biological risk assessments
- Approve containment level of laboratory
- Support Deans/Heads of Professional Services in their duty to provide sufficient training to comply with this policy.
- Attend University GM/Biological Safety Committee and escalated reports to the University Health, Safety and Environment Committee as necessary

3.5 GM/Biological Safety Committee

The GM/Biological Safety Committee shall:

- Review information and ensure that adequate discussion takes place to ensure appropriate control measures and containment is in place
- Review policy, guidance documents and protocols to ensure compliance to all relevant Biological/GM legislation
- Peer review risk assessments and aid in the classification of genetic modification work
- Review Audits undertaken across the relevant areas within Schools.
- Ensure systems and procedures align accordingly with the Human Tissue Act and association HTA committee
- Report to the Health, Safety & Environment Committee
- See Appendix 4 for membership and terms of reference

4. General Requirements And Guidance

4.1 Purchase and acquisition

The following requirements relate to both the purchase and acquisition of all biological material.

Biological material may only be procured and delivered through the University system by current members of staff and post graduate research students for use in legitimate university activities. Each School/Service must have a procedure in place to manage the authorisation, purchase, acquisition, recording and receipt of this material in line with the relevant legislation. **Currently only biological material hazard groups 1 and 2 can be purchased and GM class 1.**

Staff purchasing/acquiring biological material that require licences or registration must liaise with their SSO/DSO and the University Biological Safety Officer to ensure the university has the correct licence and the appropriate authorities are notified.

If ordering on agresso use code P_LYG for biological material and P_LYH for genetically modified material.

Prior to acquiring new cell lines or biological material, line managers/academic supervisors must ensure that a suitable biological (and if appropriate) GMO risk assessment is completed according to the requirements outline under the specific regulations.

When acquiring previously held substances, line manager/academic supervisors must ensure an up to date risk assessment exists to cover the task for which the material is to be used for.

With biological material it is important to understand the provenance of the material.

Therefore, when acquiring from other organisations it is important to get as much detail on the material (origin, what has been done to it, sequence, virulence information, screening etc).

All biological material procured or gifted into the university must be accompanied by a Material Transfer Agreement (MTA).

Please note any biological material that falls under the Human Tissue Act must go through the correct governance process. If the biological material is HTA relevant or if you believe it maybe, please contact either your School's Persons Designated (PD) or the University Designated Individual (DI) for HTA.

4.2 Inventory, Labelling and Storage

It is a requirement to know where all your biological material is stored and therefore some type of inventory is required. This listing should be electronic, backed up and secure.

Storage vessels (freezers, fridges or cryotanks) should be labelled with biohazard labels and secured where possible.

Inventories of regulated biological material such as HTA relevant or GMO's must be formally audited by the School/Service at least annually to ensure traceability. Audits must be documented, and the results kept for 3 years.

4.3 Risk assessments

All work involved with biological material needs to be risk assessed. This is to ensure safety for the employees/students and the environment but also compliance with all the regulations. The risk assessments will allow the user to understand the hazard group, GM class, whether it is HTA relevant and what containment level it must be.

The risk assessment must consider:

- Hazard group of biological material
- Provenance, cell species, tissue and cell line type
- Route of infection
- Risk factors (Enhanced virulence, low multiplication of infection)
- Infective dose (Dose of biological agent required to cause initial infection in host)
- Containment level
- Controls required
- Possible incidental exposures
- Blood borne viruses/Allergens
- Occupational health and health surveillance requirements
- Emergency arrangements

For risk assessment approval process see Appendix 1 and 2.

4.4 Transport and transfer of biological materials to other organisations

All biological material transferred between laboratories within Loughborough University should only be carried where absolutely necessary. It is important to avoid the need to carry them through communal areas or circulation routes. Where this cannot be avoided transport must be such as to avoid or reduce the risk of spillage.

All material must be transported within secondary containment, with adequate absorbent material and the associated risk assessment must include contingency plans for if the materials spills on route. Please refer to local School procedures or Biological Safety general guidance document for further information.

If you wish to transport biological material outside the university then you must consult your School's SSO/Biological Responsible Person for advice.

Transport of biological material is covered by the Carriage of Dangerous Goods and use of Transportable Pressure Equipment Regulations 2009. Speak to the UH&SS for more information.

Staff or students wishing to transfer biological material to another organisation must arrange a formal Materials Transfer Agreement (contact Research Office for further details). Please note if the biological material is HTA relevant you must contact the Designate Individual before proceeding.

4.5 Disposal and Decontamination

It is important for Schools/Services to consider the waste disposal route before purchasing or using biological material for the first time. A suitable waste disposal route must be identified. All biological material must be disposed of in a way to ensure complete deactivation. For GMO's the disposal method must be validated.

Biological/GM risk assessments must provide information relating to appropriate decontamination procedures.

All equipment which has been used in conjunction with biological material must be decontaminated and assessed for any residual risk posed before it is released for maintenance, repair or disposal. Please speak to the University Biological Safety Officer for clearance certificates.

Extractions clearance certificates must be approved and issued by UH&SS.

See guidance document on Waste Disposal, Disinfection and Decontamination of biological material for more guidance.

4.6 Emergency Arrangements

In the event of a serious incident, arrangements must be in place to make hazard information readily available to individuals (including security and external emergency services) attending the incident to enable the appropriate action to be taken.

Where there is serious risk to health, immediate steps should be taken to mitigate the effects, provide information to those who may be affected and restore the situation to normal.

Emergency procedures and arrangements should have been identified by the risk assessments; this should consider what to do in the event of fire, first aid and spills/unintended release of a biological material.

See guidance document on Incidental exposure to biological material.

4.7 Training, instruction and supervision

All staff and students must have suitable instruction and training to enable them to work with biological material safely. Instruction should include:

- Information on the biological material
- Risk to health presented using the biological material
- Relevant workplace exposure limits
- Relevant safety data information
- Biological/GM Risk assessment training
- HTA training (if applicable)
- Precautions to take to prevent or reduce exposure
- Correction operation and use of equipment and control measures
- Correct disposal route
- Emergency procedures and spill response

An appropriate level of supervision should be determined by risk assessment. Everyone working with the biological material should be able to demonstrate they are competent to use them safely.

Training needs must be reviewed on a regular basis or when there are significant changes to the work.

5. Specific Requirements

5.1 Control of Substances Hazardous to Health Regulations (COSHH) 2002

COSHH determines biological material as the following:

- Biological agent with an approved classification (i.e. known bacteria/viruses)
- Cell cultures
- Parasites that live within their host
- Bodily fluids including blood or urine

Hazard Groups and Containment

Biological agents can be classified into 4 groups based on the hazard to human health. See ACDP Approved List of Biological Agents for classification.

Hazard Group 1	Unlikely to cause disease
Hazard Group 2	May cause disease, low hazard, spread unlikely, and Prophylaxis/treatment available
Hazard Group 3	Severe disease possible, hazardous, spread possible, Prophylaxis/treatment available
Hazard Group 4	Causes severe disease, serious hazard and high risk of spread, prophylaxis/treatment not normally available.

The required degree of containments for biological material varies depending on the hazard group to which the biological material belongs. The 4 hazard groups require increasing levels of containments, designated as containment levels (CL) 1-4 (Schedule 3 COSHH). Containment level 2 and above must be signed off by UH&SS.

Biological material that has not been assigned a hazard group must be risk assessed accordingly. However, the following must always be treated as hazard group 2 or above:

- Human tissue/bodily fluids
- Unscreened cell lines
- Genetically modified cell lines
- Primary cells
- Untreated soil

Please note laboratory workers cannot work on their own bodily fluids.

COSHH risk assessments must be reviewed regularly, following any significant change, incident or where the results of any relevant exposure monitoring indicate that existing control measures are not effective.

Suitable measures must be implemented to prevent exposure to substances hazardous to health or where this is not reasonably practicable, ensure exposure is adequately controlled.

Schools/Services must ensure any engineered control measures (e.g. MSC's) are in efficient state, good repair and are within any applicable examination and testing period before use. PPE issued to staff/students must be suitable for the purpose intended, fits correctly, is stored properly and is regularly checked.

Notifications for COSHH
COSHH requires the University to notify the HSE for the following:

- First use of biological agents in Hazard Groups 2, 3 or 4.
- Subsequent use of any of the agents listed in Part V of Schedule 3 to COSHH.

5.2 Control of Substances Hazardous to Health Regulations (COSHH) 2002

The Genetically Modified Organisms (Contained Use) Regulations 2014 regulates the safe use of genetically modified organisms (GMOs) in containment. The regulations cover both the human health and environmental risks from work involving GMOs which includes modified cell cultures. For larger GMOs (animals/plants) these regulations only cover the risks to human health with the environmental risks being covered by provisions in the Environment Protection Act (EPA) and its sub-ordinate regulations.

No-one may commence any activity involving GMOs (including but not limited to, their use; culture; storage; transport; destruction; or disposal) or introduce GMOs into the environment without first consulting with the University Biological Safety Officer, undertaking a risk assessment of the activity that has been peer reviewed by the GM/Biosafety committee.

Loughborough university only has a licence for class 1 GM work. Therefore, all GM risk assessment must be approved through the GM/Biosafety Committee to ensure the work falls into this classification.

All class 1 GM work must be carried out in a containment level 2 laboratory.

6. Further Regulations

6.1 Specified Animal Pathogen Order 2008

Some biological material although only classified with an ACDP hazard group 1 may be pathogenic (harmful) to animals. It is therefore necessary to ensure the biological material you require is not classified as a Specified Animal Pathogen.

Specified Animal Pathogens in groups 2-4 will required approval from the University biological safety officer and a DEFRA licence.

SAPO Group	Classification Criteria	Containment level
1	Disease-producing organisms which are enzootic (native in animal in EU) and do not produce notifiable disease	1
2	Disease-producing organisms which are either exotic (outside EU) or produce notifiable disease, but have a low risk of spread from the laboratory	2
3	Disease-producing organisms which are either exotic or produce notifiable disease and have a moderate risk of spread from the laboratory	3
4	Disease-producing organisms which are either exotic or produce notifiable disease and have a high risk of spread from the laboratory	4

6.2 Plant Health Order 2015

Plant Health Order is concerned with controlled or prohibited plants, plant products or plant pest (Schedule 1-6).

To order, receive or work with any items covered under the Plant Health Order a Plant Health Licence will be required.

Procedures must be in place to identify activities which involve the use of category 1 or 2 precursor chemicals as outlined in EC regulation number 273/2004 and obtain a relevant licence for category 1 precursors, application to the Home Office prior to work with those substances commencing. Therefore before work can begin with these chemicals the chemical safety officer must authorised to ensure the University has the correct licence.

6.3 Anti-Terrorism, Crime and Security Act 2001

Under Schedule 5 of the Anti-Terrorism, Crime and Security Act (ATCSA) 2001 list biological material that is restricted further. Any work with biological material list under Schedule 5 Part 7 (Pathogens and toxins) requires notification to the Home Office (carried out by University Biological Safety Officer) and visits from a Counter Terrorism Security Advisor (CTSA).

Schedule 5 includes micro-organisms, nucleic acid sequences associated with pathogenicity/or GMOs and toxins.
https://www.gov.uk/guidance/secure-hazardous-materials-to-help-prevent-terrorism

7. Technical References and Further Reading

UH&SS guidance documents

http://www.lboro.ac.uk/services/health-safety/policies/guidance/

Biological Safety General guidance

Waste Disposal, Disinfection and Decontamination of biological material

Incidental exposure to biological material

Blood Borne Viruses guidance

Needlestick injuries

COSHH guidance

Procurement of Hazardous Material

HTA

HTA Licence Compliance Quality Manual

Sustainability – Waste (Resource) Management

http://www.lboro.ac.uk/services/sustainability/policy/waste/

Hazardous waste disposal procedures

Emergency spill response

Legislation

Control of Substances Hazardous to Health 2002

Genetically Modified Organisms (Contained Use) Regulations 2014

Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009

Specified Animal Pathogens Order 2008

Plant Health Order 2015

Anti-Terrorism, Crime and Security Act 2001

Animal By-Products (Enforcement) (England) Regulations 2013

The Controlled Waste (England and Wales) Regulations 2012

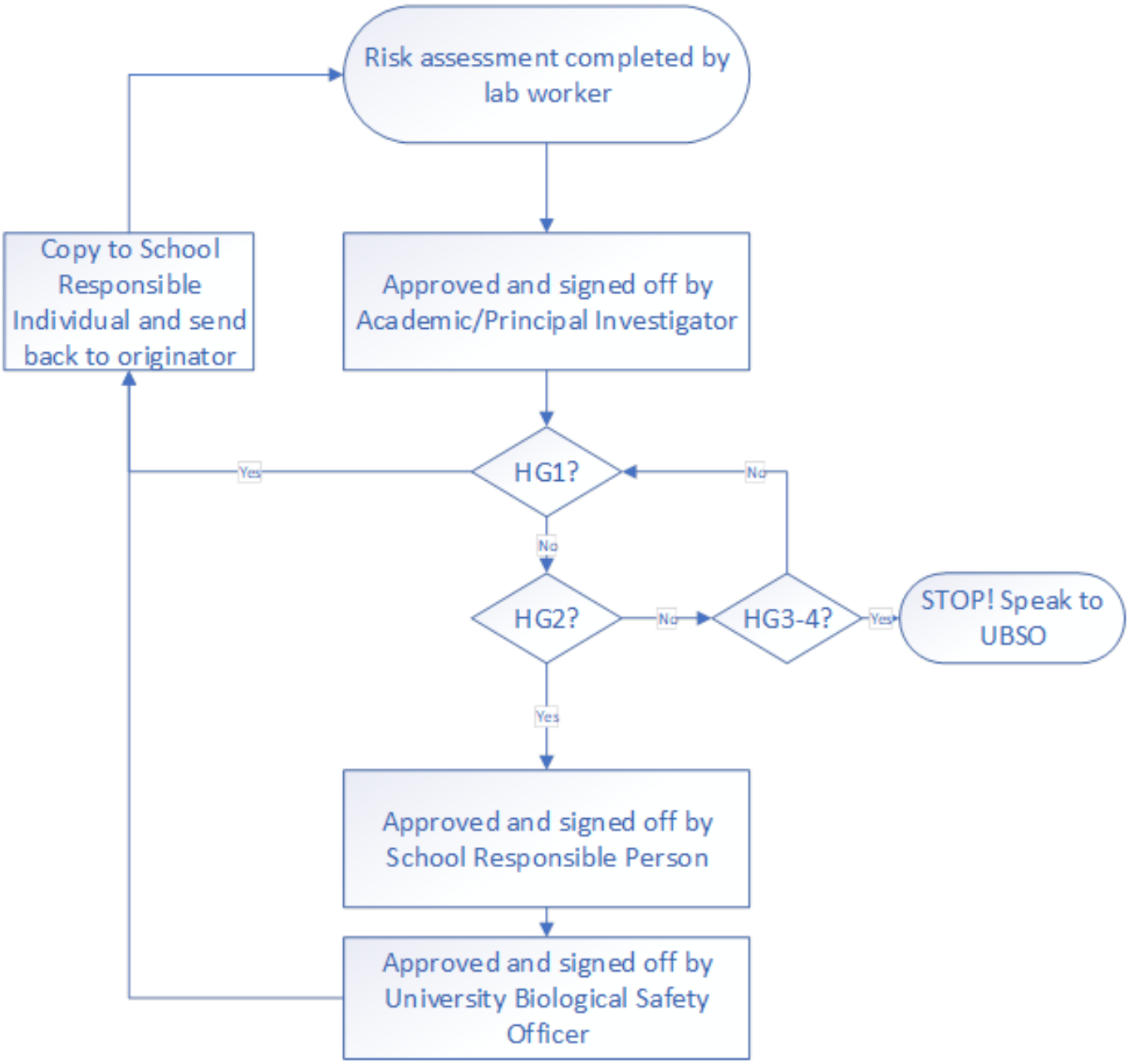
The Hazardous Waste (England and Wales) Regulations 2005

Pollution Prevention and Control Act 1999

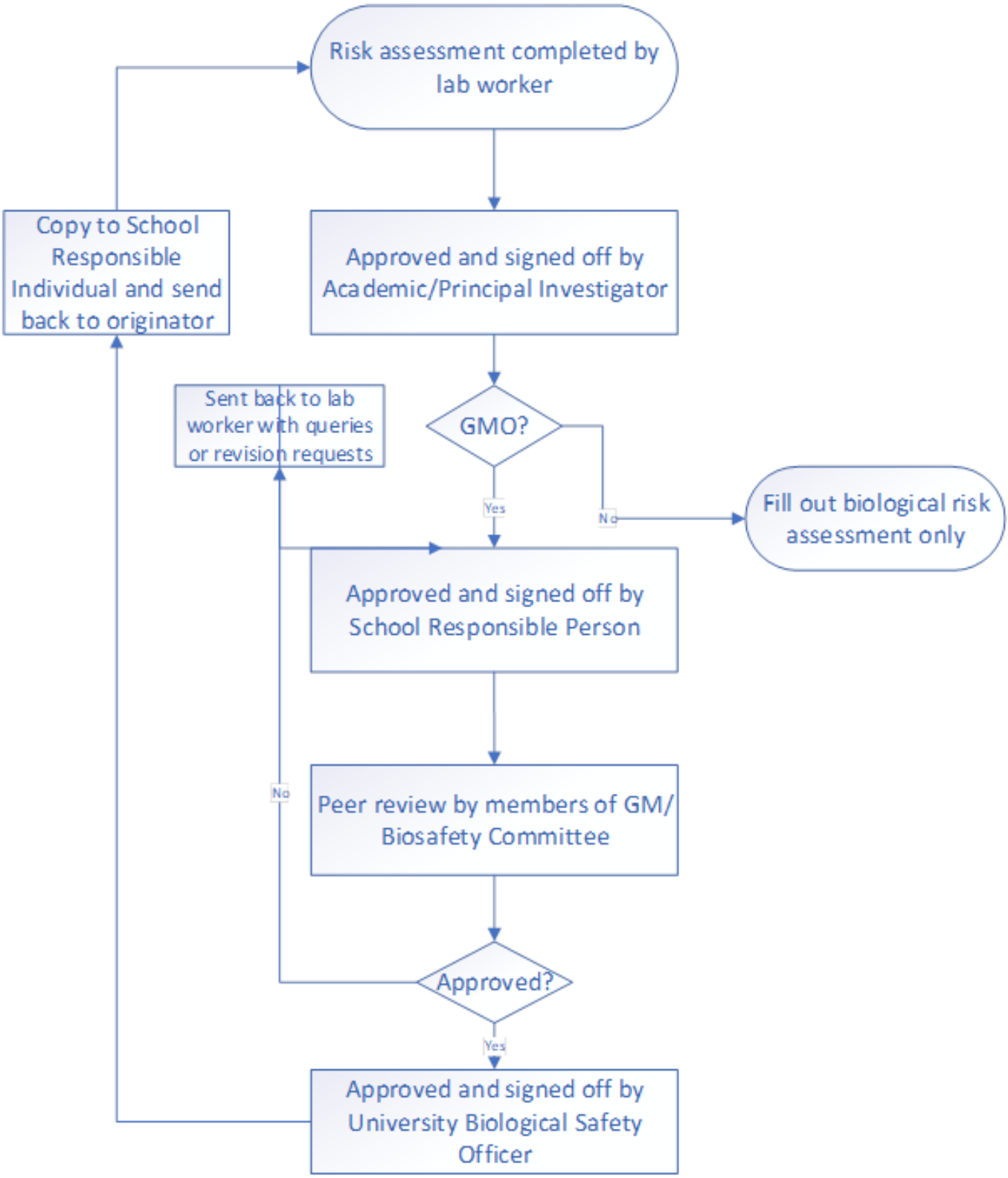
Environmental Protection Act (EPA) 1990 Part II (Waste on Land)

The Hazardous Waste (Miscellaneous Amendments) Regulations 2015

Appendix 1 - Biological Risk Assessment Sign off flowchart



Appendix 2 - GM Risk Assessment Sign off flowchart



Appendix 3 - Terms of Reference and Membership to GM/Biosafety Committee

Committee Membership

The GM/Biological Safety committee met for the first time on 21st March 2016. It was recognised that although the committee will meet twice a year on general principle, the committee may need to meet more regularly at first to align all the compliance involved with Biological, Genetic Modification and Human Tissue Act legislation into a consistent university wide system.

Member of the GM/Biological Safety Committee consists of:

Chair:

University Biological Safety Officer:
Designated Individual of HTA licence
Health, Safety & Risk Manager
Environmental Manager

School Representation:

Wolfson School x 3
SSEHS x 3

Civil & Building x1
School of Science x2

Terms of Reference

Review information and ensure that adequate discussion takes place to ensure appropriate control measures and containment is in place
Review policy, guidance documents and protocols to ensure compliance to all relevant Biological/GM legislation
Peer review risk assessments and aid in the classification of genetic modification work
Review Audits undertaken across the relevant areas within Schools.
Ensure systems and procedures align accordingly with the Human Tissue Act and association HTA committee
Report to the Health, Safety & Environment Committee

Appendix 4 - Key

ACDP	Advisory Committee on Dangerous Pathogens
CL(1-4)	Containment Level
DI	Designated Individual
GMO	Genetically Modified Organisms
HG(1-4)	Hazard Group
HTA	Human Tissue Act
LEV	Local Exhaust Ventilation
MSC	Microbiological Safety Cabinet
MTA	Material Transfer Agreement
PD	Person Designate
RP	Responsible Person
SSO	School Safety Officer
UBSO	University Biological Safety Officer
UH&SS	University Health & Safety Service